REMARKS

Reconsideration and withdrawal of the rejection of the claims of the above-identified application in view of the amendments and remarks presented herein is respectfully requested.

Claims 9-11, 15 and 17 having been amended, and claims 12-14 and 16 having been canceled, the pending claims are claims 9-11, 15 and 17.

Claim 9 has been amended to recite that an immunostimulating amount of swine plasma is administered to the animal or to the human, so as to increase disease resistance. This amendment is supported throughout the specification and working examples, e.g., at page 7, para. 1.

The doses of plasma in mg/kg are recited in claims 10-11 and are specifically supported at page 7, first paragraph.

At paragraph 8 of the Office Action, the Examiner rejected claims 9-17 under 35 U.S.C. §112(2) as indefinite for their use of the term "effective amount."

The functional term "an effective amount" is not objectionable where the amount is not critical, In re Halleck (CCPA 1970) 422 F2d 911, 164 USPQ 647, or where one skilled in the art can determine from the disclosure, including the examples, what an effective amount is, In re Watson (CCPA 1975) 517 F2d 465, 186 USPQ 11, and the function rendered effective is recited in the claim. In re Fredericksen et al.(CCPA 1954) 213 F2d 547, 102 USPQ 35; In re Caldwell (CCPA 1963) 319 F2d 254, 138 USPQ 243. As amended, claim 9 recites that the amount of swine plasma administered is effective as an immunostimulator, that increases disease resistance. Representative dosages that would be effective are given in claims 10-11, and in the working examples. Therefore, as amended, it is respectfully submitted that claim 9 fully meets the requirements of 35 U.S.C. §112(2), and withdrawal of this rejection is respectfully requested. The amendment to dependant claims 10-11, 15 and 17 to replace "a method" with "the method" moots the Examiner's rejection thereof under 35 U.S.C. §112 (2).

The amendment to claim 9 to recite that disease resistance is increased "in an animal or a human," and the amendment of claim 10 to recite "the human," moots the Examiners rejection of claims 9-10 under 35 U.S.C. §112(2).

The cancellation of claim 11 moots the Examiner's rejection thereof as set forth at para. 8(d) of the Office Action.

The amendment of claim 17 to recite that the swine plasma is administered "through" feed, veterinary pharmaceuticals, etc., moots the rejection thereof under 35 U.S.C. §112(2) as set forth at para. 8(c) of the rejection.

The amendment of claim 15 to recite that "fine-powdered Crustacea or crust of Crustacea," is used in addition to swine plasma is supported at page 7, para. 1 and in the working examples, e.g., see pages 20-21. Crust or shell of crustaceans such as eupheusid (krill) are disclosed to contain chitin or astaxanthin, as would powdered whole crustacean. The amendment to claim 15 thus meets the Examiner's rejection thereto, and withdrawal is respectfully requested.

The rejection of claims 10-11 under 35 U.S.C. §112(2) as vague and indefinite under 35 U.S.C. §112(2) on the basis that "kg" in "mg/kg" as used with reference to a daily dose of plasma is unclear is respectfully traversed. This term is one of the most conventional terms in pharmaceutical science, and when used in the context of administration of a dose of a bioactive agent to an animal or human, always refers to the weight of the subject, not to the weight of the vehicle. Although it need not be clarified in the claims, this is exactly how the term is used in the specification, e.g., at page 7. Therefore, this term fully meets the requirements of 35 U.S.C. §112 and withdrawal of this rejection is respectfully requested.

Information Disclosure Statement

Applicant submitted an Information Disclosure Statement and a 1449 Form on November 3, 2003 and October 20, 2005. The Examiner stated that the Japanese Patent 6-181656 and the French Patent 2 606 254 were non-translated documents of foreign languages. Applicants have enclosed an English Abstract for both of the above foreign language patents.

§102 Rejection of the Claims

Claims 9-17 were rejected under 35 U.S.C. §102(b) as anticipated by Suetsuna et al. (Shokuniku ni kansuru Josei Kenkyu Chosa Seika Hokokusho, i.e, Report of the Promotional Research Investigation Results of Edible Means 10 (1991); 328-334, 1992 – English translated Document of Accession number 930121753 JICST-EPlus – Applicants' IDS). Insofar as this rejection may be maintained with respect to any of the amended claims, it is respectfully traversed.

The Examiner is requested to note that the solid fractions of animal plasma are clotting factors, globulins, including immunoglobulins, and albumin. Suestsuna et al. "porcine plasma-derived peptide" or "PP" by enzymatically digesting porcine plasma (PP) with pepsin, and further processing the digest by chromatography and other procedures. Casein-derived peptide is prepared from casein, a milk protein, using the same procedure. See 2.1. This procedure is similar to that used to prepare the material designated ""swine plasma-derived peptide" or "PE" in the present application. See page 6. The swine plasma albumin or "AL" is prepared by removing fibrinogen and globulin from the swine plasma (page 6).

The Examiner is requested to consider that the point of the Suetsuna et al. studies is to compare the effects of the peptides derived by enzymatic digest of porcine plasma and casein on certain immunologocial parameters, as compared with porcine plasma and casein. There are no other controls. Thus, applicants agree with the Examiner's characterization of the reference as set forth on page 5, lines 12. However applicants respectfully disagree with the Examiner's characterization of the reference as it relates to the effect of the reference substance porcine plasma.

For example, at page 5, lines 12-15, the Examiner states that Suetsuna et al. disclose that "[r]ats administered with porcine plasma...showed significantly high[er] natural killer activity" (see section 3.4, Fig. 4 and page 8) and "significantly increased phagocytosis of opsonized sheep RBCs" (see section 3.6, Figure 5, page 8 and first paragraph on page 10). While porcine-plasma-derived peptide showed improved parameters as compared to porcine plasma, porcine plasma did not increase any immune function, and usually resulted in the poorest results.

In section 3.4 it is disclosed that "a significantly high NK activity was observed particularly in the PP diet group [rather] than in the P diet group (Figure 4)." Figure 4 shows that the porcine plasma P group exhibited the lowest NK activity, and that this activity was not elevated over any standard. Page 8 also discloses that "the tendency for a significantly higher [NK] activity was observed particularly in the PP diet group [rather] than in the P diet group. "Figure 5 shows that the phagocytosis of AMØ was lowest in the case of the porcine plasma diet, of all the diets tested. Page 8 discloses that the AmØ phagocytosis was high[er] in the peptide (CP, PP) diet groups than in the protein (C, P) diet groups, and a significant difference ($p<0.05$) was observed." Page 10 discloses the same results.

Thus, Suetsuna does not disclose or suggest a method of increasing disease resistance in animals or humans by administering an immunostimulating amount of porcine plasma, alone or with crustacea or crustacea shells. The motivation of the authors' work was to study peptidyl extracts or subunits of biological materials, not to study animal plasma as a dietary supplement. One of skill in the art in possession of Suetsuna et al. would be strongly motivated to digest casein or porcine plasma with pepsin to yield a peptidyl fraction that could then be used to improve the immune function of animals over that observed in animals fed a plasma or casien diet. Therefore, withdrawal of this rejection is appropriate and is respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6905 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date 3-14-06

By _____
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 14th day of March, 2006.

PATRICIA A. HULTMAN

Name

Signature